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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,633	03/19/2001	Thomas L. Benjamin	00742-066001	1354

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EXAMINER

LI, QIAN J

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,633

Applicant(s)

BENJAMIN ET AL.

Examiner

O. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 135).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in the National application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-12 are drawn to a method comprising the step of determining whether there is a proliferative disease-associated alteration in a *Sal2* nucleic acid in a mammal. Classified in class 435, subclass 6.
- II. Claims 13-18 are drawn to a method comprising the step of determining whether there is a proliferative disease-associated alteration in a *Sal2* protein in a mammal. Classified in class 435, subclass 7.1.
- III. Claims 19-22 are drawn to a knockout mouse comprising a mutation in a genomic m*Sal2* gene. Classified in class 800, subclass 13.
- IV. Claims 23-30 are drawn to a transgenic mouse whose genome comprises a nucleic acid construct including a *Sal2* nucleic acid. Classified in class 800, subclass 13.
- V. Claim 31 is directed to a cell line comprising a *Sal2* transgene in the cellular genome. Classified in class 435, subclass 455.
- VI. Claims 32-37 are drawn to a method of killing an abnormally proliferating cell. Classified in class 435, subclass 456.
- VII. Claims 38-45 are drawn to a method of identifying a compound that alters cell proliferation by measuring whether said compound alters proliferation of cells. Classified in class 435, subclass 32.

VIII. Claims 46, 47, 49, and 52 are drawn to a method of identifying a compound that alters cell proliferation by measuring whether said compound alters *Sal2* protein levels in a cell or cell extract. Classified in class 435, subclass 7.1.

IX. Claims 46, 48, and 50 52 are drawn to a method of identifying a compound that alters cell proliferation by measuring whether said compound alters *Sal2* nucleic acid levels in a cell or cell extract. Classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II, VI-IX and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention is drawn to different methods for diagnosis for changes in *Sal2* protein and nucleic acid levels, for cell killing, or for identifying a compound by evaluating cell proliferation, *Sal2* protein or nucleic acid levels. The different methods have different method steps, use different starting material and different testing criteria, have different modes of operation, and distinct technical considerations. For example, the method steps and detecting agents used for measuring changes in *Sal2* protein levels in group VIII would differ from that of nucleic acid levels in group IX; the starting materials used for cell killing in group VI would be different from the determination of the cellular *Sal2* protein alteration of group VII.

Inventions IV, V, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention is drawn to different products. The different products are Sal2 transgenic or knockout mice, and a cell line comprising a Sal2 transgene. The mice in each of invention III and IV have distinct phenotype and genotype, made by different method, thus, each have distinct technical considerations. Although the cell line could be obtained from the transgenic mouse, it can also be made by a different method and could be used in materially different processes. Further, a cell and an animal, each belongs to a distinct chemical entity, have different search criteria and technical considerations.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The differences of the Inventions I-IX are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Clark can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-

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1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
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QJL

March 5, 2002



JAMES KETTER
PRIMARY EXAMINER